



# MEDI-CAL UPDATE

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[www.medi-cal.ca.gov](http://www.medi-cal.ca.gov)

Pharmacy Bulletin 635

July 2006

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## Medi-Cal List of Contract Drugs

The following provider manual sections have been updated: *Drugs: Contract Drugs List Part 1 – Prescription Drugs*, *Drugs: Contract Drugs List Part 2 – Over-the-Counter Drugs* and *Drugs: Contract Drugs List Part 4 – Therapeutic Classifications Drugs*.

### Addition, effective May 24, 2006

<u>Drug</u>	<u>Size and/or Strength</u>	<u>Billing Unit</u>
‡ DECITABINE Injection	50 mg/vial	ea

### Addition, effective June 28, 2006

<u>Drug</u>	<u>Size and/or Strength</u>	<u>Billing Unit</u>
‡ *DARUNAVIR Tablets	300 mg	ea
* Restricted to use as combination therapy in the treatment of Human Immunodeficiency Virus (HIV) infection.		

### Addition, effective June 29, 2006

<u>Drug</u>	<u>Size and/or Strength</u>	<u>Billing Unit</u>
‡ DASATINIB Tablets	20 mg	ea
	50 mg	ea
	70 mg	ea

*Please see Contract Drugs, page 3*

## EDS/MEDI-CAL HOTLINES

Border Providers .....(916) 636-1200  
CDHS Medi-Cal Fraud Hotline .....1-800-822-6222  
Telephone Service Center (TSC) .....1-800-541-5555  
Provider Telecommunications Network (PTN).....1-800-786-4346

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*For a complete listing of specialty programs and hours of operation, please refer to the Medi-Cal Directory in the provider manual.*



**OPT OUT** is a new service designed to save time and increase Medi-Cal accessibility. A monthly e-mail containing direct Web links to current bulletins, manual page updates, training information, and more is now available. Simply “opt-out” of receiving this same information on paper, through standard mail. To download the OPT-OUT enrollment form or for more information, go to the Medi-Cal Web site at [www.medi-cal.ca.gov](http://www.medi-cal.ca.gov), and click the “Learn how...” OPT OUT link on the right side of the home page.

## Stop Illegal Tobacco Sales

The simplest way to stop illegal tobacco sales to minors is for merchants to check ID and verify the age of the tobacco purchasers. Report illegal tobacco sales to 1-800-5-ASK-4-ID.

For more information, see the California Department of Health Services Web site at <http://www.dhs.ca.gov>.

## MEDI-CAL FRAUD IS AGAINST THE LAW

MEDI-CAL FRAUD COSTS TAXPAYERS MILLIONS  
EACH YEAR AND CAN ENDANGER  
THE HEALTH OF CALIFORNIANS.

HELP PROTECT MEDI-CAL AND YOURSELF  
BY REPORTING YOUR OBSERVATIONS TODAY.

**CDHS MEDI-CAL FRAUD HOTLINE**  
**1-800-822-6222**

**THE CALL IS FREE AND YOU CAN REMAIN ANONYMOUS.**

Knowingly participating in fraudulent activities can result in prosecution and jail time. Help prevent Medi-Cal fraud.

**Contract Drugs** (*continued*)**Additions, effective August 1, 2006**

<b><u>Drug</u></b>	<b><u>Size and/or Strength</u></b>	<b><u>Billing Unit</u></b>
INSULIN DETEMIR (rDNA origin) + Injection	100 Units/cc      10 cc	cc
ROSIGLITAZONE MALEATE/GLIMEPIRIDE + Tablets	4 mg/1 mg 4 mg/2 mg 4 mg/4 mg	ea ea ea

**Changes, effective August 1, 2006**

<b><u>Drug</u></b>	<b><u>Size and/or Strength</u></b>	<b><u>Billing Unit</u></b>
AMLODIPINE <b><u>BESYLATE</u></b> /BENAZEPRIL <b><u>HYDROCHLORIDE</u></b> + Capsules	<b><u>2.5 mg – 10 mg</u></b> <b><u>5 mg – 10 mg</u></b> <b><u>5 mg – 20 mg</u></b> <b><u>10 mg – 20 mg</u></b> <b><u>5 mg – 40 mg</u></b> <b><u>10 mg – 40 mg</u></b>	<b><u>ea</u></b> <b><u>ea</u></b> <b><u>ea</u></b> <b><u>ea</u></b> <b><u>ea</u></b> <b><u>ea</u></b>
OMEPRAZOLE/ <b><u>SODIUM BICARBONATE</u></b> Powder packet	20 mg 40 mg	
<b><u>Capsules</u></b>	<b><u>20 mg</u></b> <b><u>40 mg</u></b>	
<b><u>VALSARTAN/HYDROCHLOROTHIAZIDE</u></b> + Tablets	80 mg – 12.5 mg 160 mg – 12.5 mg 160 mg – 25 mg <b><u>320 mg – 12.5 mg</u></b> <b><u>320 mg – 25 mg</u></b>	ea ea ea <b><u>ea</u></b> <b><u>ea</u></b>

**Changes, effective September 1, 2006**

<b><u>Drug</u></b>	<b><u>Size and/or Strength</u></b>	<b><u>Billing Unit</u></b>
SIMVASTATIN + Tablets	5 mg 10 mg 20 mg 40 mg 80 mg	ea ea ea ea ea
<b><u>(NDC Labeler Code 00006 [MERCK CO. INC])</u></b>		

+ Frequency of billing requirement

*These updates are reflected on manual replacement pages drugs cdl p1a 6, 37 and 38, drugs cdl p1b 28, drugs cdl p1c 11 and 37, drugs cdl p1d 2 and 20 and drugs cdl p4 6, 7 and 12 thru 14 (Part 2).*

### Waterproof Sheeting Update Affecting Acquisition Cost, Transition Period and Quantity Limit

Effective for dates of service on or after August 1, 2006, providers can purchase waterproof sheeting from the contracted manufacturers listed below using the new Maximum Acquisition Cost (MAC). Reimbursement to providers based on the new MAC price is effective for dates of service beginning October 1, 2006.

For dates of service on or before September 30, 2006, providers may bill both contracted products and non-contracted products. When billing using code 9947A TI or 9947A VS in that time period, providers are reimbursed according to the pricing in effect prior to June 1, 2006 or on the basis of a catalog page or invoice.

Effective for dates of service on or after October 1, 2006, all manufacturers' products not included in a contract will no longer be a Med-Cal benefit, will not be granted prior authorization or a *Treatment Authorization Request* (TAR), and will not be reimbursed.

The quantity limitation of three (3) in a 365-day period, which would have taken effect on September 1, 2006, has been rescinded. Quantity limitations for waterproof sheeting will continue at a maximum of two (2) in a 365-day period, per recipient, unless approved through prior authorization.

<u>Manufacturer</u>	<u>Description</u>	<u>Stock Number</u>	<u>UPC</u>	<u>MAC</u>	<u>Billing Code</u>
<b>G. Hirsch &amp; Company Inc.</b>					
	Poly/Vinyl Quilted, with Anchor band, 39" x 75"	SR 832	000891832001	\$22.00	9947A TI
	Cooltex with Bactishield, 36" x 72"	SR 837	000891837006	\$22.00	9947A TI
<b>Humanicare International, Inc.</b>					
	Sheeting, Waterproof, Quilted rubber free hypoallergenic 36" x 80"	36080	(01)00044156360809	\$22.00	9947A VS
	Sheeting, Waterproof, Quilted rubber free hypoallergenic 39" x 75"	39075	(01)00044156390752	\$22.00	9947A VS

*These updates are reflected on manual replacement page mc sup lst3 14 (Part 2).*

**DRUG USE REVIEW**  
*Educational Information***Use of Topical Calcineurin Inhibitors in the Medi-Cal  
Fee-For-Service (FFS) Population**

On March 10, 2005 the Food and Drug Administration (FDA) issued a Public Health Advisory for the topical calcineurin inhibitors Pimecrolimus Cream (Elidel®) and Tacrolimus Ointment (Protopic®)<sup>1</sup>.

On January 19, 2006, the FDA approved updates to the product labels and a *Patient Medication Guide* to be given to patients receiving pimecrolimus cream and tacrolimus ointment<sup>2</sup>.

Pimecrolimus cream and tacrolimus ointment are topical immunosuppressant calcineurin inhibitors that are applied to the skin, and are the only approved drugs in this class.

The FDA's concerns are based on information from animal studies, case reports in small numbers of patients and on the mechanism of action of the drugs<sup>1</sup>.

- Although a causal relationship has not been established, there have been rare cases of malignancy reported in patients being treated with topical calcineurin inhibitors
- Phase I animal data suggest that the risk of cancer increases with increased exposure to topical pimecrolimus or tacrolimus
- Long-term safety data of these drugs has not been established

The FDA and the manufacturers recommend that healthcare providers, patients and caregivers consider the following<sup>1,3,4</sup>.

- Use as ***second-line treatment*** in patients unresponsive to, or intolerant of, other treatments (e.g. topical corticosteroids)
- Indicated for ***short-term*** and ***intermittent*** treatment of mild to moderate atopic dermatitis (eczema)
- Avoid the use of pimecrolimus and tacrolimus in children younger than 2 years of age. The effect of these agents on the developing immune system in infants and children is not known
- Do not use in patients with a weakened or compromised immune system
- Use the minimum amount of pimecrolimus and tacrolimus needed to control the patient's symptoms

Topical pimecrolimus and tacrolimus are NOT indicated in children less than 2 years old and high-dose tacrolimus (0.1%) is NOT indicated in children less than 16 years of age.<sup>4</sup>

For more information on label changes or to obtain Patient Medication Guides, visit:

**[www.fda.gov/bbs/topics/news/2006/NEW01299.html](http://www.fda.gov/bbs/topics/news/2006/NEW01299.html)**

*Please see Topical Calcineurin, page 6*

**Topical Calcineurin** (*continued*)

Medi-Cal conducted a retrospective study of beneficiaries with paid pharmacy claims for calcineurin inhibitors. Patients with at least one pharmacy paid claim for a calcineurin inhibitor between July 1, 2005 and December 31, 2005 were included in the analysis. The claims for these beneficiaries were analyzed for an 18-month lead-in period of January 1, 2004 through June 30, 2005 to determine if prescribing patterns were appropriate, including the trial/failure of another agent prior to initiation of treatment with a calcineurin inhibitor. It should be noted that only oral prednisone, oral methylprednisolone and topical corticosteroids were considered to determine previous therapies. Medi-Cal also recognizes that other agents (i.e. prednisolone, oral dexamethasone, Vitamin D analogs, etc.) can be used to treat eczema that were not included in this analysis.

There were a total of 714 continuously eligible beneficiaries identified who received a calcineurin inhibitor agent during the study period (July 1, 2005 through December 31, 2005).

- 22 percent of patients began treatment with a topical calcineurin inhibitor drug *before* trial/failure of a topical corticosteroid, oral prednisone, or oral methylprednisolone
- 15 percent of all patients with paid claims for topical calcineurin inhibitors were infants less than 2 years old
- 36 percent of all patients ages 2 through 15 with a paid claim for tacrolimus ointment were treated with the high dose (0.1 percent) strength

Medi-Cal is monitoring the utilization of all topical calcineurin inhibitors for appropriate use.

To report any unexpected adverse events associated with these agents, contact the FDA MedWatch program at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, HFD-410, 5600 Fishers Lane, Rockville, MD, 20857-9787; or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

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<sup>1</sup> FDA Public Health Advisory Elidel (pimecrolimus) Cream and Protopic (tacrolimus) Ointment. Food and Drug Administration, March 10, 2005. [http://www.fda.gov/cder/drug/advisory/elidel\\_protopic.htm](http://www.fda.gov/cder/drug/advisory/elidel_protopic.htm)

<sup>2</sup> FDA News FDA Approves Updated Labeling with Boxed Warning and Medication Guide for Two Eczema Drugs, Elidel and Protopic. Food and Drug Administration, January 19, 2006. <http://www.fda.gov/bbs/topics/news/2006/NEW01299.html>

<sup>3</sup> ELIDEL (Pimecrolimus, Novartis) Package Insert. <http://www.pharma.us.novartis.com/product/pi/pdf/elidel.pdf>

<sup>4</sup> PROTOPIC (Tacrolimus, Astellas Pharma Inc.) Package Insert. <http://www.astellas.us/docs/protopic.pdf>

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## Instructions for Manual Replacement Pages

July 2006

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## Part 2

### Pharmacy Bulletin 635

Remove and replace:

- drugs cdl p1a 5/6 and 37/38
- drugs cdl p1b 27/28
- drugs cdl p1c 11/12 and 37
- drugs cdl p1d 1/2 and 19/20
- drugs cdl p4 5 thru 8 and 11 thru 14
- mc sup lst3 13/14

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### DRUG USE REVIEW (DUR) MANUAL

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Remove from the  
*Education* section:

36-31

Insert:

36-31 thru 33 \*